

REMARKS

Applicants have amended the specification to reflect the status of all pending parent Applications.

For the sake of clarity, claims 40-54, 58-60, 62-71, 75 and 82-107 have been canceled and new claims 108-145 have been submitted. Claims 108-112, 115-129 and 132-145 substantially track the canceled claims.

Claim 108 substantially tracks canceled claim 40. However, claim 108 has been drafted so that the claimed method is drawn towards the need to vaccinate an animal against herpesvirus. Support for the language of claim 108 can be found in the specification, for example, on page 5, lines 19-21, through page 6, lines 1-2.

Claims 125 and 142 substantially track canceled claims 71 and 75, respectively. However, claims 125 and 142 have been drafted so that the claimed methods are drawn specifically towards determining the immune-status of an animal against herpesvirus. Furthermore the claims specify that the animal being tested must have been vaccinated against herpesvirus at least six months prior to testing. Support for the language of claims 125 and 142 can be found, for example, in canceled claims 71 and 75, as well as in the specification, for example, on page, 5, lines 19-21, and page 38, lines 5-6.

Furthermore, claims 108, 125 and 142 all specify the recombinant protein used in the claimed methods must comprise at least 300 contiguous amino acids from specific herpesvirus-related SEQ ID NO's. Similarly, claims 109 and 126 specify the recombinant protein used in the claimed methods must comprise at least 400 contiguous amino acids from specific herpesvirus-related SEQ ID NO's. Support for such language can be found in the specification, for example, on page 13, lines 16-20, and on page 15, lines 2-5.

Claims 110-112, 127-129 and 145-146 track canceled claim 66.

Claims 113-114 specify the presence of a complex indicates the animal need not be vaccinated whereas the absence of a complex indicates the animal needs to be vaccinated. Similarly, claims 130-131 specify the presence of a complex indicates the animal is immune to herpesvirus infection whereas the absence of a complex indicates the animal is susceptible to herpesvirus infection. Support for these claims can be found in the specification, for example, on page 40, lines 2-5, and on page 30, lines 7-18.

Claims 115-124 and 132-141 track canceled claims 43-54.

In view of the above, Applicants submit no new matter has been entered into the application.

I. Election/Restriction

The Examiner has maintained restriction of the present claims to a single organism and a single sequence from that organism. The Examiner has also stated that SEQ ID NO's 18, 20 and 22 would be examined together.

While Applicants disagree with the Examiner's restriction, in the interest of expediting prosecution, Applicants have submitted a new claim set which substantively tracks the previous claim set, but which are drawn solely to herpesvirus and SEQ ID NO's 18, 20 and 22.

II. Specification

Applicants note a priority paragraph has been added to the specification as requested by the Examiner.

III. Rejections Under 35 USC §112, first paragraph – written description

The Examiner has rejected claims 40, 65-68, 83, 84, 87, 88, 93-96 and 102-105 as failing to comply with the written description requirement. Specifically, the Examiner states that while the claims cover all mutated, truncated and structural homologs of the disclosed sequences, Applicants have only disclosed the sequence of SEQ ID NO:22. The Examiner further states that while Applicants have provided written description for SEQ ID NO:22, Applicants have not disclosed fragments or homologs which have the functional characteristics claimed.

Applicants note the rejected claims have been canceled. Moreover claims 110-112, 127-129 and 145-146 each specify the use of full length SEQ ID NO:18, 20 or 22, which the Examiner has admitted have adequate written description.

With regard to claims 108, 109, 125, 126 and 142, these claims state the recombinant protein used in the claimed method must have at least 300 or 400 contiguous amino acids from specific SEQ ID NO's. Applicants believe 300 and 400 contiguous amino acid fragments of SEQ ID NO:18, 20 and 22 are adequately described for the following reasons.

First, Applicants have disclosed the full length sequences of SEQ ID NO's 18, 20 and 22, which are 534, 469 and 469 amino acids in length, respectively. Thus it follows that 300 or 400 contiguous amino sequences from these SEQ ID NO's have also been disclosed. With regard to

which portions of the disclosed SEQ ID NO's would have the necessary activity to practice the claimed method, Applicants believe that any 300-400 contiguous amino acid portion from SEQ ID NO:18, 20 or 22 would meet such a requirement. Applicant's contention is based on the size of the claimed portions relative to the size of the full-length proteins. As noted, SEQ ID NO's 18, 20 and 22 are 534, 469 and 469 amino acids in length, respectively. Thus a 300 amino acid sequence represents 56%, 64% and 64%, while a 400 amino acid sequence represents 75%, 85% and 85% of SEQ ID NO:18, 20 or 22, respectively. Therefore more than half of all possible epitopes present in SEQ ID NO:18, 20 or 22 would be present in a 300 contiguous amino acid fragment from these sequences; the number of epitopes represented jumps to at least 75% in the case of a sequence which is at least 400 contiguous amino acids in length. Applicants contend, therefore, that since the sera being tested would inherently be polyclonal in nature, it is more than likely that a 300 or 400 contiguous amino acid sequence from SEQ ID NO:18, 20 or 22 would bind antibodies which were originally made against the full length protein(s). Therefore, Applicants believe the 300 and 400 contiguous amino acid fragments in the newly submitted claim set are adequately described.

IV. Rejections Under 35 USC §103 – Obviousness

The Examiner has rejected claims 40-54, 60, 63-71, 75, 83, 84, 87, 88 and 90-107 as being unpatentable over Hoffmann-Lehmann *et al.*, in view of Prud'homme *et al.*, in further view of Maeda *et al.* The Examiner states that Hoffman-Lehmann *et al.* describe a method of determining the prevalence of antibodies to feline herpesvirus using ELISA and IFA. The Examiner further states that while Hoffman-Lehmann *et al.* use crude antigens instead of recombinant antigen, Prud'homme *et al.* describe a competitive ELISA for detecting alphaherpesvirus antibodies using recombinant herpesvirus glycoprotein antigen gp50. Additionally, the Examiner states that Maeda *et al.* disclose the nucleotide sequence (and therefore the corresponding amino acid sequence) of FHV type I glycoprotein C which aligns with the instantly claimed SEQ ID NO:22. The Examiner concludes it would have been obvious to use the protein of Maeda in the assay of Hoffmann-Lehmann instead of any herpesvirus antigen since Maeda suggests the application of this protein as an important subunit vaccine in immunity for FHV-1 infection in cats.

As noted in the MPEP §2142, in order to establish a *prima facie* case of obviousness, the prior art references must teach or suggest all of the claim limitations. Applicants contend the cited prior art fails to establish such a case since the cited references fails to teach every element of the claimed invention.

First, Applicants note claim 108 is drawn to a method to determine the need to vaccinate an animal for herpesvirus. In doing so, the instant invention correlates the presence of antibodies to herpesvirus protein in an animal with the need to vaccinate that animal. None of the cited prior art references teach or suggest this element of the invention. Hoffmann-Lehmann *et al.* measure anti-herpesvirus antibody levels in free-ranging lions, but do not teach or suggest whether such animals need to be vaccinated based on the levels observed. Similarly, Prud'homme *et al.* measure the levels of antibodies to pseudorabiesvirus gp50 in pigs but provide no teaching or suggestion to use the results to determine whether such animals require vaccination. Furthermore, Maeda *et al.* fail to remedy the lack of teaching in either Hoffmann-Lehmann *et al.* or Prud'homme *et al.* Maeda merely provides the sequence of a feline herpesvirus glycoprotein C. Thus Applicants contend that even if the cited references were combinable, which Applicants disagree, one would not reach the instant invention.

Next, a similar argument applies to claims 125 and 142. Both of these claims are drawn to a method to determine the herpesvirus-related immune status of an animal which was previously vaccinated against herpesvirus. A critical element of the claimed methods is the obtainment of a sample from an animal previously vaccinated against herpesvirus. The disclosure of such an element is lacking in any of the cited prior art references; nor is such an element suggested by any of the prior art references. Thus as was stated above, Applicants contend that even if the cited references were combinable, one would not reach the instant invention.

Therefore, with regard to claims 108, 125 and 142, Applicants contend the Examiner has failed to establish a *prima facie* case of obviousness.

Finally, with regard to SEQ ID NO's 18 and 20, Applicants note these sequences are not taught in the prior art cited by the Examiner. The Examiner has stated that the sequence of Maeda *et al.* aligns with SEQ ID NO:22. However, the sequence of Maeda *et al.* does not align with SEQ ID NO:18 or 20. Applicants note that SEQ ID NO's 18 and 20 have a valine at positions 273 and 240, respectively, whereas Maeda *et al.* teaches a glycine at the corresponding

position (i.e., amino acid position 273). For the Examiner's convenience, Applicants have submitted as Exhibit A an alignment of the sequence of Maeda (Accession No. D86616) with SEQ ID NO's 18 and 20; the difference in the sequences has been highlighted with asterisk. Therefore, since Maeda *et al.* do not teach one element of the invention, namely the amino acid sequence of SEQ ID NO's 18 or 20, Applicants contend Maeda *et al.* is not prior art against claims 109, 111, 128, 129 or 146.

In view of the above, Applicants request withdrawal of the obviousness rejection under 35 U.S.C §103(a).

CONCLUSION

All of the pending Claims are believed to be in condition for allowance. In the event the Examiner has any questions regarding this Application, the Examiner is invited to contact the undersigned representative at (970) 493-7272, ext. 4174.

Respectfully submitted,

Dated: October 25, 2006

By:



Richard J. Stern, Ph.D.
Registration No. 50,668
Heska Corporation
3760 Rocky Mountain Avenue
Loveland, Colorado 80538
Telephone: (970) 493-7272
Facsimile: (970) 619-3011